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Proposed Registration Decision PRD2016-35

Ammonia (present as ammonium carbamate)

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Overview

Proposed Registration Decision for Ammonia (present as Ammonium Carbamate)

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Technical Ammonium Carbamate and Spectrum XD1878 Chlorine Stabilizer, containing the technical grade active ingredient ammonia (present as ammonium carbamate), to control bacteria, fungi, and associated slimes in process water used in pulp and paper mills and recirculating cooling water systems.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Technical Ammonium Carbamate and Spectrum XD1878 Chlorine Stabilizer.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

Before making a final registration decision on ammonia (present as ammonium carbamate), the PMRA will consider any comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on ammonia (present as ammonium carbamate), which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is Ammonia (present as ammonium carbamate)?

Ammonium carbamate provides a source of ammonia (NH_3) used to generate chloramines, which are oxidizing biocides that are effective against biofilms. Chloramines are formed by reaction of ammonia with sodium hypochlorite *in situ* within a feeding device. Chloramines are less powerful oxidizing agents than chlorine and kill microbes by destroying cell wall components and proteins.

Health Considerations

Can Approved Uses of Ammonia (present as ammonium carbamate) Affect Human Health?

Ammonia (present as ammonium carbamate) is unlikely to affect human health when it is used according to label directions.

Potential exposure to ammonia (present as ammonium carbamate) may occur when handling the end-use product, Spectrum XD1878 Chlorine Stabilizer. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100 times higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

In laboratory animals, the technical grade active ingredient ammonia (present as ammonium carbamate) was slightly acutely toxic via the oral route and was of low toxicity via the dermal route. It was moderately irritating to the eyes, non-irritating to the skin, and was not a dermal sensitizer. Consequently the signal words "CAUTION POISON" and "WARNING EYE IRRITANT" are required on the label for the active ingredient.

In laboratory animals, the end-use product Spectrum XD1878 Chlorine Stabilizer was of low toxicity via the oral, dermal and inhalation routes. It was severely irritating to the eye, non-irritating to the skin, and was not considered as a dermal sensitizer. Consequently the signal words "DANGER EYE IRRITANT" are required on the end-use product label.

Registrant-supplied waivers for short- and long-term (lifetime) animal toxicity tests, as well as available information from the published scientific literature were assessed for the potential of ammonia (present as ammonium carbamate) to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The available information suggests that ammonia (present as ammonium carbamate) is unlikely to have any short- or long-term effects. Furthermore, consideration was given to the anticipated low exposure potential resulting from the intended use of the end-use product in a highly automated, closed system, as well as the dietary and occupational exposure aspects outlined below.

Residues in Water and Food

The use of Spectrum XD1878 Chlorine Stabilizer in pulp and paper industry for the production of food-contact paper can result in indirect dietary exposure to the residues of monochloramine; however, such exposure is not expected to result in an unacceptable risk when Spectrum XD1878 Chlorine Stabilizer is used according to the label directions.

No risk due to exposure from drinking water is anticipated from the proposed use.

Risks in Residential and Other Non-Occupational Environments

Estimated risk for non-occupational exposure is not of concern when directions specified on the label are observed.

Occupational Risks From Handling Spectrum XD1878 Chlorine Stabilizer

Occupational risks are not of concern when Spectrum XD1878 Chlorine Stabilizer is used according to label directions, which include protective measures.

Occupational exposure to individuals handling Spectrum XD1878 Chlorine Stabilizer is not expected to result in unacceptable risk when the product is used according to label directions. Precautionary and hygiene statements on the product label aimed at mitigating worker exposure are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Due to the requirement for closed loading and transfer of Spectrum XD1878 Chlorine Stabilizer to the feeder/delivery system, an enclosed system, direct exposure to workers from handling the end-use product, such as manually pouring, mixing, or sampling is not possible.

Dermal or inhalation exposure to Spectrum XD1878 Chlorine Stabilizer, however, is possible for workers when hooking up the bulk container to the feeder/delivery system, removal of the spent container, and during clean-up and repair activities. In addition, accidental exposure to the eyes may occur if the product is splashed during handling. Therefore, mitigation through personal protective equipment (PPE) requirements and additional precautionary and hygiene statements will be required on the end-use product label.

Post-application activities, such as coupling or uncoupling of transfer lines may result in exposure of workers to residual biocide from treated process waters. However, exposure is expected to be low when following the required PPE and precautionary and hygiene statements on the product label.

Bystander exposure is not possible as non-workers are not expected to be present in the wastewater treatment plant, and the end-use product is to be used in a closed system.

Environmental Considerations

What happens when ammonia (present as ammonium carbamate) is introduced into the environment?

Ammonia (present as ammonium carbamate) is not expected to pose risks of concern to the environment when used according to the label directions.

Technical Ammonium Carbamate and Spectrum XD1878 Chlorine Stabilizer are to be used to control bacteria and fungi and associated slimes in pulp and paper industrial process waters and recirculating cooling water systems. The end-use product is applied in conjunction with sodium hypochlorite to form monochloramine, a substance which will control microbes in water. Monochloramine, which is the primary chemical of environmental concern with the use of Spectrum XD1878 Chlorine Stabilizer, may enter the environment through effluent discharge to rivers, streams, or other waterbodies, including marine systems. Although levels in effluent are expected to be low, monochloramine is toxic to aquatic organisms. A label statement requiring the dechlorination of effluent to undetectable levels of total chlorines prior to discharge will be required, where applicable.

Value Considerations

What Is the Value of Spectrum XD1878 Chlorine Stabilizer?

Spectrum XD1878 Chlorine Stabilizer is used for the control of biofilm in pulp & paper mills and recirculating cooling water systems.

In paper mills and recirculating cooling towers, biofilms (slimes) can form on equipment surfaces such as paper machines and heat exchangers. Slime buildup is often associated with hydrogen sulfide production, which is corrosive to the metal machinery beneath the biofilm. Sloughing off of the biofilms may lead to defects in the final paper sheet and disruptions in the paper making process. In addition, bacterial and fungal growth can lead to spoilage of pulp resulting in significant waste and economic losses. Biofilm growth on the heat exchangers within cooling water systems acts like an insulator, reducing the efficiency of heat transfer. While ammonia as a precursor to chloramine formation is currently registered, Spectrum XD1878 Chlorine Stabilizer provides a different chemistry to generate chloramines.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Spectrum XD1878 Chlorine Stabilizer to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The personal protective equipment for all loading, clean-up and repair activities required on the end-use product label includes protective eyewear, coveralls or long pants and long sleeved shirt, chemical resistant gloves, socks and chemical resistant footwear.

Environment

A label statement requiring the dechlorination of effluent to undetectable levels of total chlorines prior to discharge is required due to the toxicity of monochloramine to aquatic organisms.

Next Steps

Before making a final registration decision on ammonia (present as ammonium carbamate), the PMRA will consider any comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document.

Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

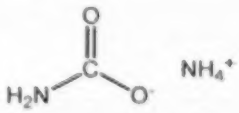
When the PMRA makes its registration decision, it will publish a Registration Decision on ammonia (present as ammonium carbamate) to control bacteria, fungi, and associated slimes in process water used in pulp and paper mills and recirculating cooling water systems (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Ammonia (present as ammonium carbamate)

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Ammonia, present as ammonium carbamate
Function	Slimicide
Chemical name	
1. **International Union of Pure and Applied Chemistry (IUPAC)**	Ammonia, present as ammonium carbamate
2. **Chemical Abstracts Service (CAS)**	Ammonia, present as carbamic acid, ammonium salt (1:1)
CAS number	1111-78-0
Molecular formula	$CH_6N_2O_2$
Molecular weight	78.07
Structural formula	
Purity of the active ingredient	21.6% ammonia, present as ammonium carbamate

1.2 Physical and Chemical Properties of the Active Ingredient and End-Use Product

Technical Product—Technical Ammonium Carbamate

Property	Result
Colour and physical state	White granular solid
Odour	Moderate to strong ammonia odour
Melting point	58.19°C
Boiling point or range	N/A
Density at 20°C	1.4028 g/cm^3
Vapour pressure at 20°C	9.02×10^3 Pa
Ultraviolet -visible spectrum	No absorbance expected at $\lambda > 300$ nm

Solubility in water at 20°C	> 430 g/L
Solubility in organic solvents	Not expected to be soluble in most organic solvents
n-Octanol-water partition coefficient (K_{ow})	N/A
Dissociation constant (pK_a)	Titration with 0.02 M hydrochloric acid resulted in one pK_a of 8.91 and a second pK_a of 6.55; titration with 0.02 M sodium hydroxide resulted in a pK_a of 10.0.
Stability (temperature, metal)	Ammonium carbamate readily degrades to ammonia and carbon dioxide which is lost to the atmosphere but the remaining ammonium carbamate retains its purity. Approximately 18.5% loss of product was observed after one month at room temperature. At elevated temperature (54°C), considerable loss of product was observed after 1-2 days.

End-Use Product—Spectrum XD1878 Chlorine Stabilizer

Property	Result
Colour	Colourless
Odour	Strong ammonia odour
Physical state	Liquid
Formulation type	Solution
Guarantee	4.46% ammonia, present as ammonium carbamate
Container material and description	Plastic drums and tanker truck
Density	1.139 g/cm^3
pH	9.82 (1% solution in water); 10.53 (neat)
Oxidizing or reducing action	Ammonium carbamate is a reducing agent.
Storage stability	The product is stable for 1 year when stored in plastic containers at ambient temperature.
Corrosion characteristics	The product is non-corrosive to the packaging material.
Explodability	The product is not explosive.

1.3 Directions for Use

Spectrum XD1878 Chlorine Stabilizer controls bacteria, fungi and associated slimes in the process water of pulp and paper mill and recirculating cooling water systems. The mixing is done at a ratio of 1 L of sodium hypochlorite (12%) with 0.7 kg of Spectrum XD1878 Chlorine Stabilizer. Sufficient biocide is added to achieve and maintain a measured concentration of 0.5-10.0 ppm for paper mill systems and 0.3-5.0 ppm residual biocide for cooling waters, expressed as total chlorine.

1.4 Mode of Action

The chloramines formed by the use of Spectrum XD1878 Chlorine Stabilizer are oxidizing biocides that kill microbes by destroying cell walls and proteins. They are less powerful oxidizing agents than chlorine or chlorine dioxide and therefore are not consumed by weaker reducing agents, making them more available to target biofilms.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and impurities in Technical Ammonium Carbamate have been assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation has been assessed to be acceptable for use as an enforcement analytical method.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed review of the submitted toxicology studies, data waiver rationales, published scientific literature, and other publicly available information for the active ingredient ammonia (present as ammonium carbamate) was conducted. The scientific quality of the data is acceptable and the database is sufficiently complete to define the majority of the toxic effects that may result from exposure to ammonium carbamate when used as intended as a pest control product.

Ammonia (present as ammonium carbamate) is slightly acutely toxic by the oral route and is of low toxicity by the dermal route. It is moderately irritating to the eyes, non-irritating to the skin, and is not a dermal sensitizer. A data waiver request for the acute inhalation toxicity for ammonia (present as ammonium carbamate) was accepted as it volatilizes upon exposure to air and dissociates into ammonia and carbon dioxide; therefore, a stable atmosphere of the test compound cannot be established and maintained for an accurate inhalation toxicity study.

Spectrum XD1878 Chlorine Stabilizer is of low toxicity by the oral, dermal and inhalation routes, severely irritating to the eye, and non-irritating to the skin. It is not considered to be a skin sensitizer.

The applicant requested waivers from the short-term, chronic, developmental toxicity, immunotoxicity and mutagencity data requirements for ammonia (present as ammonium carbamate) based on the following rationale: 1) the proposed use of ammonia from ammonium carbamate, as a precursor chemical for generation of monochloramine, involves negligible, if any, oral, dermal or inhalation exposure; 2) the generation process occurs in a highly automated, closed system with no manual handling of the precursor materials or the resulting monochloramine; and 3) ammonia (present as ammonium carbamate) essentially forms

ammonium carbonate/bicarbonate upon aqueous dilution, which are considered safe for human consumption. Food grade ammonium carbonate consists of ammonium carbonate, ammonium bicarbonate and ammonium carbamate.

Moreover, there is sufficient information available in the public domain to complete an assessment of the toxicology of ammonia and from which an adequate safety determination for ammonium carbamate can be made. Ammonia (present as ammonium carbamate) is not expected to be carcinogenic, genotoxic, neurotoxic, or a developmental or reproductive toxicant.

3.1.1 Incident Reports

Since ammonia (present as ammonium carbamate) is a new active ingredient pending registration for use in Canada, there are no incident reports. Once products containing this active ingredient are registered, the PMRA will monitor for incident reports.

3.2 Occupational, Residential, and Bystander Risk Assessment

3.2.1 Dermal Absorption

Dermal absorption is expected to be low as there is no direct handling of Spectrum XD1878 Chlorine Stabilizer to result in prolonged dermal exposure.

3.2.2 Use Description

Spectrum XD1878 Chlorine Stabilizer is proposed for industrial use as a slimicide for treating water systems in pulp and paper mills and recirculating cooling water systems. It is to be used in conjunction with a registered sodium hypochlorite solution (12.5% w/w) and the Spectrum XD1878 Chlorine Stabilizer feeder/delivery system, which is programmed to automatically and optimally produce a dilute solution of chloramine. The generated chloramine is added continuously or intermittently with uniform mixing to the process waters for which treatment is required depending on the severity of the contamination. It is the monochloramine that will exhibit the biocidal properties.

Spectrum XD1878 Chlorine Stabilizer and sodium hypochlorite are supplied in large containers or by tanker trucks, and all feeds, reactions and outputs occur in a closed environment. The monochloramine production process is controlled by a Programmable Logic Controller (PLC). The PLC is programmed to start and stop the operation of the system; therefore, there is no direct exposure in handling—for example, manually pouring, mixing or sampling—of the precursor chemicals. The PLC controls the reaction process so that the proper amount of monochloramine is produced. If there is a system failure, the PLC can shut down the whole operation.

For pulp and paper mill water systems, Spectrum XD1878 Chlorine Stabilizer is mixed with a 12.5% sodium hypochlorite solution at the rate of 0.7 kg Spectrum XD1878 Chlorine Stabilizer to 1.0 L of sodium hypochlorite, intended to achieve a measured concentration of 0.5-10.0 ppm residual biocide expressed as total chlorine, and maintained.

For recirculating cooling water systems (such as, industrial cooling towers, evaporative condensers, heat exchange water towers, and influent systems, such as flow through filters and industrial water scrubbing systems), a measured concentration of 0.3-5.0 ppm residual biocide expressed as total chlorine is to be achieved and maintained.

3.2.3 Mixer, Loader and Applicator Exposure and Risk

Occupational exposure to Spectrum XD1878 Chlorine Stabilizer is expected to be low. Due to the requirement for closed loading and transfer of Spectrum XD1878 Chlorine Stabilizer to the feeder/delivery system, an enclosed system, direct long-term exposure to workers from handling the end-use product, such as manually pouring, mixing, or sampling is not possible.

However, dermal or inhalation exposure to Spectrum XD1878 Chlorine Stabilizer is possible for workers when hooking up the bulk container to the feeder/delivery system, removal of the spent container, and during clean-up and repair activities. Accidental exposure to the eyes may occur if the product is splashed during handling.

Personal protective equipment requirements on the end-use product label instruct workers to wear protective eyewear, protective clothing, and protective gloves when handling the product. Additional precautionary and hygiene statements instruct workers to avoid contact with skin, eyes and clothing, to avoid breathing the vapour, to wash thoroughly with soap and water after handling, and to remove contaminated clothing and wash before reuse. Exposure of workers to Spectrum XD1878 Chlorine Stabilizer will be appropriately mitigated through the requirements for PPE, observing precautionary and hygiene statements, and the nature of the closed system where the end-use product will be used. Therefore, occupational exposure to Spectrum XD1878 Chlorine Stabilizer is expected to be low when workers follow the label directions.

3.2.4 Post-Application Exposure and Risk

There is a potential for worker exposure to residual monochloramine from treated process waters during post-application activities, such as coupling or uncoupling transfer lines. However, post-application exposure is expected to be low when workers follow the required PPE and precautionary and hygiene statements on the product label.

3.2.5 Residential and Bystander Exposure Risk

As Spectrum XD1878 Chlorine Stabilizer is to be used in a closed system in industrial settings where bystanders are not expected to be present, no bystander exposure to the end-use product is expected to occur.

3.3 Food Residue Exposure Assessment

3.3.1 Food and Drinking Water

Although there is no direct food use for Spectrum XD1878 Chlorine Stabilizer, the use in pulp and paper industry for the production of food-contact paper can result in indirect dietary exposure to the residues of monochloramine; however, such exposure is not expected to be of concern when Spectrum XD1878 Chlorine Stabilizer is used according to the label directions.

There is no drinking water exposure concern from the proposed use because monochloramine is used in drinking water disinfection. According to the Guidelines for Canadian Drinking Water Quality, the maximum acceptable concentration of chloramines in drinking water is 3 ppm.

3.3.2 Maximum Residue Levels (MRLs)

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether the consumption of the maximum amount of residues that are expected to remain on food products when a pesticide is used according to label directions, will not be a concern to human health. This maximum amount of residues expected is then legally established as a MRL under the *Pest Control Products Act* for the purposes of adulteration provision of the *Food and Drugs Act* (FDA). Health Canada sets science-based MRLs to ensure the food Canadians eat is safe.

As no direct food or feed uses are proposed, specifying the establishment of a MRL under the *Pest Control Products Act* is not required.

4.0 Impact on the Environment

For the purpose of this evaluation, information from the Environment Canada and Health Canada Priority Substance List Assessment Report for inorganic chloramines was used.

4.1 Fate and Behaviour in the Environment

Spectrum XD1878 Chlorine Stabilizer (in other words, ammonia, present as ammonia carbamate) is mixed with sodium hypochlorite to form monochloramine, a relatively slow-acting oxidizing microbicide. Once formed, monochloramine will readily transform into multiple compounds (other inorganic chloramines, organic chloramines, ammonia, and free chlorine). This closely related group of reaction products is collectively referred to as monochloramine residuals, which are typically measured in terms of mg Cl_2/L (total chlorine).

The fate of monochloramine residuals once discharged into the environment is influenced by water-phase processes, including dilution, mixing, advection, chemical demand, benthic demand, photodegradation, volatilization, sediment adsorption and reaction, and sediment associated transport, deposition, burial and resuspension. Considering all processes, available data suggest that monochoramines have a half-life of 2 to 41 days. As such, monochloramine residuals can be categorized as non-persistent to slightly persistent in aquatic systems.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations to which adverse effects occur. Estimated environmental concentrations (EECs) are concentrations of pesticide in various environmental media. In the context of this assessment, water was the media of interest. The EECs are estimated using standard models which may take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide. Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints.

Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicology endpoints in risk assessments may be adjusted by applying an uncertainty factor to account for potential differences in species sensitivity as well as varying protection goals (that is, protection at the community, population, or individual level). A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC). If the screening level RQ is below the LOC, the risk is considered negligible and no further risk characterization is necessary. If the screening level RQ is equal to or greater than the LOC, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios. If the generation of quantitative data is not practical for a particular active ingredient/product, a qualitative assessment may be more appropriate.

The risk assessment for Spectrum XD1878 Chlorine Stabilizer is quantitative (screening level risk assessment) and qualitative (refined risk assessment).

4.2.1 Risk to Terrestrial Organisms

Based on the proposed use pattern in industrial process waters, the use of Spectrum XD1878 Chlorine Stabilizer is not expected to result in terrestrial exposure; therefore, risk to non-target terrestrial species is expected to be limited.

4.2.2 Risk to Aquatic Organisms

The toxicity of monochloramine (resulting from the use of Spectrum XD1878 Chlorine Stabilizer) to aquatic organisms as well as the screening level RQs are presented in Appendix I, Tables 1-3.

Non-target aquatic organisms may be exposed to monochloramine residues through effluent discharge. Facilities may be located in proximity of either freshwater or marine water bodies and both environments were considered in the risk assessment. Through chemical reactions within

the treatment system, and through biological degradation during secondary treatment, the amount of monochloramine discharged into the aquatic environment through the use of the product Spectrum XD1878 Chlorine Stabilizer is expected to be below the level of detection, measured as total chlorine. The level of detection for total chlorine is typically 0.01 or 0.02 mg/L, depending on the analytical method that is used. The higher value, 0.02 mg/L was chosen as the EEC for this review because this is the more conservative value of the two.

Even at very low concentrations, monochloramine residuals can be toxic to aquatic organisms. A screening level risk assessment, comparing toxicity values for groups of aquatic organisms to a concentration of 0.02 mg total chlorine/L in undiluted effluent, indicates some risk to non-target aquatic organisms (Appendix I, Table 3).

The refined risk assessment took into consideration factors such as dilution and dechlorination of the effluent. Inorganic chloramines are expected to be quickly diluted to non-detectable levels if rapid mixing occurs in a sufficient volume of surface water. If, however, dilution of the effluent is limited or if the current velocity is fast, complete mixing may not occur for several kilometres downstream from the source and concentrations of monochloramine residuals may persist for some distance. As a precaution to further mitigate the risk to aquatic organisms, a label statement requiring dechlorination (to non-detectable concentrations of total chlorines) of industrial process water prior to discharge into the environment is required.

5.0 Value

5.1 Consideration of Benefits

Biofilms are typically made up of a large number of different bacterial and fungal microorganisms. As biofilms mature they tend to form a polysaccharide coating that protects the microbes within the biofilm from the effects of biocide treatment. Within paper mills and cooling towers, operators frequently alternate biocides over time as the biofilms adapt to a particular treatment regime. More than 40 different active ingredients or combinations of active ingredients are registered for use as slimicides for pulp and paper and cooling water (see Appendix I, Table 4). In general, chloramines have been shown to be an effective alternative biocide for biofilm control.

Oxidizers are efficient biocides that can maintain good microbial control with low doses and short contact times. They are a cost effective solution to many microbial problems within process waters and are one of the most widely used classes of biocides for biofilm control. However, strong oxidizing biocides such as chlorine or chlorine dioxide tend to react with weak reducing agents. In process waters high in organic matter, strong oxidizers can be consumed by oxidizing the organic matter rather than controlling the biofilm. In addition, reactions with some weak reducing agents can result in the formation of undesirable chlorinated disinfection by products. The chloramines formed with Spectrum XD1878 Chlorine Stabilizer have a relatively low oxidation potential, and as such are consumed less by high organic loads. Furthermore, its potential for producing halogenated by-products is much lower than that of strong oxidizing biocides.

5.2 Effectiveness Against Pests

Data were provided from operational use trials at three different paper mills and a cooling tower in which Spectrum XD1878 Chlorine Stabilizer was used to replace a previous biocide regime. In these operational case studies, a number of parameters were monitored, including chloramine levels, bacterial and fungal counts, bio-sludge formation, oxygen saturation and oxidation-reduction potential over periods ranging from several months to two years. These data demonstrated the ability of Spectrum XD1878 Chlorine Stabilizer to control bacteria, fungi and biofilm in a variety of pulp and paper mills and cooling towers.

5.3 Non-Safety Adverse Effects

No non-safety adverse effects were identified for the use of Spectrum XD1878 Chlorine Stabilizer as a slimicide used in paper mills and cooling towers.

5.4 Supported Uses

See Appendix I, Table 5.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy: that is, persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, Technical Ammonium Carbamate, and reaction chemicals including monochloramine, were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Technical Ammonium Carbamate does not meet all Track 1 criteria, and is not considered a Track 1 substance. Ammonium carbamate is unstable in water and dissociates rapidly to ammonium hydroxide and carbamic acid. Carbamic acid further dissociates in equilibrium with the predominant species being ammonium, carbonate and bicarbonate ions.
- Transformation products of Technical Ammonium Carbamate do not meet the Track 1 criteria. Available data suggest that monochoramines have a half-life of 2 to 41 days in water (non-persistent to slightly persistent).

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[5] DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy.*

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[6]. The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including DIR99-03 and DIR2006-02[8], and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Technical Ammonium Carbamate and the end-use product Spectrum XD1878 Chlorine Stabilizer do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

7.0 Summary

7.1 Human Health and Safety

The available information for the active ingredient ammonia (present as ammonium carbamate) is adequate to qualitatively identify the toxicological hazards that may result from human exposure to the end-use product, Spectrum XD1878 Chlorine Stabilizer. Ammonia (present as ammonium carbamate) is considered to be slightly acutely toxic by the oral route and is moderately irritating to the eyes. Spectrum XD1878 Chlorine Stabilizer is severely irritating to the eyes.

Occupational exposure to Spectrum XD1878 Chlorine Stabilizer is expected to be low if the precautionary statements and recommended PPE on the product label, which are intended to minimize worker exposure, are observed. Bystander exposure is not expected based on the product's use in closed industrial systems.

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6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

7 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

8 DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

7.2 Environmental Risk

A potential concern to fresh water and marine organisms from the use of Spectrum XD1878 Chlorine Stabilizer (due to the formation of monochloramine) was identified during the risk assessment. To mitigate potential toxic levels of monochloramine residuals present in effluent discharged to the environment, a label statement directing facilities to conduct dechlorination of process water when detectable concentrations of total chlorines are measured is required. Standard environmental label statements for products than can be released into aquatic environment will also apply. With these mitigation measures, this product is not expected to pose risks of concern to non-target organisms.

The chemicals of concern, monochloramine and residuals, are not expected to build-up in the environment under the current use pattern and, with mitigation measures in place, exposure to non-target organisms is expected to be low. Risk to the environment through this use is expected to be minimal.

7.3 Value

Thick biofilms can produce hydrogen sulfide resulting in significant corrosion to the metal machinery within paper mills and cooling towers. Biofilms can also cause issues with paper quality and paper producing operations and result in lower efficiency of heat transfer in cooling towers. The data submitted in support of Spectrum XD1878 Chlorine Stabilizer were adequate to demonstrate its efficacy in controlling biofilms within pulp and paper mills and recirculating cooling water systems. As the chloramines formed by mixing Spectrum XD1878 Chlorine Stabilizer with sodium hypochlorite are weaker oxidizing agents than other biocides such as chlorine dioxide, less are consumed by organic matter in the process water and are more available to act on the biofilm. Spectrum XD1878 Chlorine Stabilizer provides an alternative biocide for the treatment of fouled systems. This product can contribute to controlling biofilm thereby reducing disruption in the paper making process in pulp and paper facilities and maintaining heat transfer efficiency in cooing water towers.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Technical Ammonium Carbamate and Spectrum XD1878 Chlorine Stabilizer, containing the technical grade active ingredient ammonia (present as ammonium carbamate), to control bacteria, fungi, and associated slimes in process water used in pulp and paper mills and recirculating cooling water systems.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

♀	female
♂	male
λ	wavelength
a.i.	active ingredient
bw	body weight
°C	degree Celsius
CAS	Chemical Abstracts Service
CBI	confidential business information
cm	centimetres
DACO	data code
EC_{50}	effective concentration on 50% of the population
EEC	estimated environmental concentration
g	gram
hr	hour
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{ow}	*n*–octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOC	level of concern
mg	milligram
MAS	maximum average score
MIS	maximum irritation score
MRL	maximum residue limit
N/A	not applicable
NH_3	ammonia
nm	nanometer
M	molar
OECD	Organization for Economic Cooperation and Development
Pa	pascal
PCPA	Pest Control Products Act
p*K*a	dissociation constant
PLC	programmable logic controller
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
RA	risk assessment
Reg. No.	*Pest Control Products Act* registration number
RQ	risk quotient
SI	stimulation index
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
w/w	mass per mass percentage

Appendix I Tables and Figures

Table 1 Acute Toxicity Profile of Technical Ammonium Carbamate (100% w/w)

Study Type/Animal/PMRA #	Study Results
Acute toxicity	
Acute oral toxicity Rat, Crl: CD(SD) albino PMRA# 2479198	LD_{50} ♀ = 1080 mg/kg bw Slightly acutely toxic
Acute Dermal Toxicity Rat, Crl: CD(SD) albino PMRA# 2479199	LD_{50} ♂ & ♀ > 5000 mg/kg bw Low toxicity
Acute Inhalation Toxicity Data waiver request PMRA# 2479203	A stable atmosphere of ammonium carbamate cannot be established as it gets volatized into ammonia and carbon dioxide.
Eye Irritation Rabbit, New Zealand White PMRA# 2479200	MAS[a] = 21.4/110 MIS[b] = 24/110 (48 hours) Moderately irritating to the eye (Based on the MAS and non-resolution of eye irritation)
Dermal Irritation Rabbit, New Zealand White PMRA# 2479201	MAS[a] = 0/8 MIS[b] = 0/8 Non-irritating to the skin
Dermal Sensitization (Local Lymph Node Assay) CBA/J mice PMRA# 2479202	Test substance did not elicit an SI[c] ≥ 3 SI[c] value for positive control = 45.5 Not a dermal sensitizer

[a]MAS = Maximum Average Score for 24, 48, and 72 hours
[b]MIS = Maximum Irritation Score (average)
[c]SI = Stimulation index

Table 2 Acute Toxicity Profile of Spectrum XD1878 (20% a.i.)

Study Type/Animal/PMRA #	Study Results
Acute toxicity	
Acute oral toxicity Rat, Crl: CD(SD) albino PMRA# 2479237	LD_{50} ♀ = 3400 mg/kg bw Low toxicity
Acute Dermal Toxicity Rat, Crl: CD(SD) albino PMRA# 2479238	LD_{50} ♂ & ♀ > 5000 mg/kg bw Low toxicity
Acute Inhalation Toxicity Rat, Crl: CD(SD) albino PMRA# 2479239	LC_{50} (♂,♀) > 1.9 mg/L Low toxicity
Eye Irritation Rabbit, New Zealand White PMRA# 2479240	MAS[a] = 30.5/110 MIS[b] = 36.7/110 (48 hours) Severely irritating to the eye (Based on the MAS and non-resolution of eye irritation)
Dermal Irritation Rabbit, New Zealand White PMRA# 2479241	MAS[a] = 0/8 MIS[b] = 0/8 Non-irritating to the skin

[a]MAS = Maximum Average Score for 24, 48, and 72 hours
[b]MIS = Maximum Irritation Score (average)

Table 3 Screening level risk assessment (RA) for inorganic chloramine for non-target aquatic organisms[a]

Organism	Toxicity value	RA endpoint = Toxicity value / Uncertainty factor	EECb[b]	RQ[c]
Freshwater invertebrate *Ceriodaphnia dubia*	Incipient LC_{50} = 0.018 mg/L	0.018/2 = 0.009 mg/L	0.02 mg/L	**2.2**
Marine invertebrate *C. dubia* (toxicity endpoint surrogate)	Incipient LC_{50} = 0.018 mg/L	0.018/2 = 0.009 mg/L	0.02 mg/L	**2.2**
Freshwater fish Chinook salmon	Incipient LC_{50} = 0.09 mg/L	0.09/10 = 0.009 mg/L	0.02 mg/L	**2.2**
Marine fish *Menidia menidia*	96 hours LC_{50} = 0.04 mg/L	0.04/10 = 0.004 mg/L	0.02 mg/L	**5**
Marine Algae *Porphyra yezoensis*	10 day EC_{50} (growth) = 0.014 mg/L	0.014/2 = 0.007 mg/L	0.02 mg/L	**2.9**

[a]Toxicity values were obtained from PMRA# 2138222
[b]EEC = estimated environmental concentrations based on the conservative level of detection for total chlorine.
[c]RQ = risk quotient

Table 4 Registered alternatives

Type of active ingredient	Examples of an end-use product with active ingredient (Reg. No.[a])
Alkyl Trimethylenediamines	19863
Hydantoins	26986
Isothiazolones	25660
Bronopol	21790
Quaternary ammonium compounds	25503
Glutaraldehyde	28686
Oxidizers	26166, 25258, 30179
Carbamates	18619

[a]Reg. No.= *Pest Control Products Act* Registration Number

Table 5 List of Supported Uses

Proposed label claim	Supported use claim
Pulp & Paper Mill Water Systems: 0.5 – 10.0 ppm total chlorine Recirculating Cooling Water Systems: 0.3 – 5.0 ppm total chlorine	Accepted as proposed.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
2479186	2014, Chemistry for TGAI, DACO: 2.1,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9 CBI
2479187	2013, Ammonium Carbamate: Product identity and Composition; Description of starting materials used to product the product and the formulation process; Discussion of the potential impurity formation; certification of limits and Analytical enforcement, DACO: 2.11.1,2.11.2,2.11.3,2.11.4,2.12.1,2.13.1,2.13.2 CBI
2479188	2013, Preliminary Analysis of Ammonium Carbamte Active Ingredient, DACO: 2.13.3 CBI
2479189	2013, Sample Analysis of Ammonium Carbamate Produced by [Privacy Info Removed], DACO: 2.13.3 CBI
2479190	2012, Impurity Analysis of Technical ammonium Carbamate, DACO: 2.13.4 CBI
2479191	2012, Product chemistry for ammonium Carbamate Following OCSPP Series 830 and OECD Guidelines, DACO: 2.14.1,2.14.15,2.14.2,2.14.3,830.7000 CBI
2479192	2013, Ammonium Carbamate - Determination of the Stability of a Technical Grade Product Following OCSPP Guideline 830.6313, DACO: 2.14.13,2.14.14 CBI
2479193	2013, Product chemistry testing for ammonium carbamate following OCSPP guidelines series 830 and OECD Guidelines, DACO: 2.14.10,2.14.4,2.14.6 CBI
2479194	2013, Ammonium Carbamate - Determination of the water solubility of a test substance following OCSPP Guideline 830.7840 and OECD Guideline 105, DACO: 2.14.7 CBI
2479195	2013, Ammonium Carbamate - Determination of the Vapour Pressure by the static procedure following OCSPP Guideline 830.7950 and OECD Guideline 104, DACO: 2.14.9 CBI
2479196	2013, Ammonium Carbamate - Determination of the Mass Spectra, DACO: 2.14.12 CBI

2479197	2014, Chemistry waivers, DACO: 2.14.11,2.14.5,2.14.8 CBI
2560388	2015, Ammonium Carbamate Discussion, DACO: 2.13.3 CBI
2560389	2015, Ammonium Carbamate Discussion for XD1878, DACO: 2.13.3 CBI
2479206	2014, Waiver Requests for Environmental Chemistry and Fate Data Requirements, DACO: 8.1,8.2.2.2,8.2.2.3,8.2.2.4,8.2.3.1,8.2.3.2,8.2.3.3.2,8.2.3.5.4,8.2.3.5.6,8.2.4.1,8.2.4.2,8.4.1CBI
2546452	2015, Updated Registrant Address, DACO: 2.1 CBI
2546458	2014, Preliminary Analysis of Ammonium Carbamate Following OCSPP Guideline 830.1700 and Regulation (EU) 528/2012, DACO: 2.13.3 CBI
2546460	2015, Updated Description – [Privacy Info Removed], DACO: 2.11.2 CBI
2546462	2015, Updated Description – [Privacy Info Removed], DACO: 2.11.2 CBI
2546464	2015, Updated Production Process, DACO: 2.11.3 CBI
2546465	2015, Updated Batch data information, DACO: 2.13 CBI
2565033	2015, Preliminary Analysis of Ammonium Carbamate Following OCSPP Guideline 830.1700 and Regulation (EU) 528/2012, DACO: 2.13.3 CBI
2567764	2014, Impurity Analysis of Technical Ammonium Carbamate, DACO: 2.13.4 CBI
2479231	2014, Product Identification, DACO: 3.1.1,3.1.2,3.1.3,3.1.4 CBI
2479232	2013, Spectrum XD1878: Product identity and Composition; description of Materials Used to produce the Product and the Formulation Process; Discussion of Potential Impurity Formation; Certified Limits and Enforcement Analytical Method, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.4.1,3.4.2 CBI
2479233	2013, Product Chemistry Testing for XD-1878 Following OCSPP Series 830 and OECD Guidelines, DACO: 3.5.1,3.5.2,3.5.3,3.5.7,3.5.9 CBI
2479234	2014, General Chemical/Physical Properties, DACO: 3.5.11,3.5.12,3.5.13,3.5.15,3.5.4,3.5.5,3.5.8 CBI
2479235	2013, Determination of the density of XD-1878, DACO: 3.5.6 CBI
2479236	2013, Review of XD1878 Storage Stability results for time zero through time 6 months including corrosion, DACO: 3.5.10,3.5.14 CBI
2546476	2015, Raw Material Sources List, DACO: 3.2.1 CBI
2546477	2015, Spectrum™ XD1878 – Determination of Storage Stability under Controlled Conditions Following Product Properties Test Guideline OCSPP 830.6317, DACO: 3.5.10,3.5.14 CBI
2546478	2015, Updated Address, DACO: 3.1.1 CBI

2546479	2015, Clarification on material, DACO: 3.5.10,3.5.14 CBI
2573026	2015, Clarification Response to manufacturing and plastic constiners, DACO: 3.2.2,3.5.10,3.5.14 CBI

2.0 Human and Animal Health

PMRA Document Number	Reference
2479198	2013, Acute Oral Toxicity Study of Ammonium Carbamate in albino Rats (Up-and-down Procedure), DACO: 4.2.1
2479199	2013, Acute Dermal Toxicity Study of Ammonium Carbamate in Albino Rats, DACO: 4.2.2
2479200	2013, Acute Eye Irritation Study of Ammonium Carbamate in Albino Rabbits, DACO: 4.2.4
2479201	2012, Acute Dermal Irritation study of Ammonium Carbamate in Albino Rabbits, DACO: 4.2.5
2479202	2013, Assessment of Contact Hypersensitivity to ammonium carbamate in the mouse (local lymph node assay), DACO: 4.2.6
2479203	2013, technical Ammonium Carbamate, Request for waiver for acute inhalation, OSCPP Guideline No. 870.1300, DACO: 4.2.3
2479204	2014, Discussion of Toxicology Data Requirements, Including Waiver Requests, for the Use of the Active Ingredient Ammonia from Ammonium Carbamate as a precursor to generate Monochloramine, in Papermill Process Water and Recirculating Cooling Water Treatment, DACO: 4.3.1,4.3.5,4.4.1,4.4.2,4.4.3,4.5.1,4.5.2,4.5.3,4.5.4,4.5.5,4.5.7,4.5.9
2479205	2014, Toxicology Report Summaries, DACO: 4.1
2479237	2013, Acute oral toxicity of spectrum XD1878 in Albino Rats (Up-and-down Procedure), DACO: 4.6.1
2479238	2013, Acute Dermal Toxicity of Spectrum XD1878 in Albino Rats, DACO: 4.6.2
2479239	2013, Acute Inhalation Toxicity of Spectrum XD1878 in Albino Rats, DACO: 4.6.3
2479240	2013, Acute Eye Irritation Study of Spectrum XD1878 in Albino Rabbits, DACO: 4.6.4
2479241	2013, Acute Dermal Irritation Study of Spectrum XD1878 in Albino Rabbits, DACO: 4.6.5
2479243	2014, Summaries - Tox profile, DACO: 4.1
2479244	2014, Discussion of Occupational Exposure Data Requirements, Including Waiver Requests, for the Use of the Spectrum XD1878, in Papermill Process Water and Recirculating Cooling Water Treatment 9 % Ammonia present as Ammonium Carbamate, DACO: 5.1,5.3,5.4,5.5

2479245	2014, Use Description/Exposure Scenario for the Use of the Spectrum XD1878, in Paper mill Process Water and Recirculating Cooling Water Treatment, DACO: 5.2

3.0 Value

PMRA Document Number	Reference
2479247	2014, General Value Summaries, DACO: 10.1,10.2.1,10.2.2,10.2.3.1,10.3.1,10.3.2,10.5
2554142	2015, NAC: biocide produced on site from XD1878 and Sodium Hypochlorite Efficacy Data - Summary Report, DACO: 10.2.3.4(A)
2554143	2015, NAC: biocide produced on site from XD1878 and Sodium Hypochlorite Efficacy Data – COOLING WATER Summary Report, DACO: 10.2.3.4(A)
2554144	2015, Summary of Benefits/Options, DACO: 10.3.2,10.4,10.5.1,10.5.3

B. Additional Information Considered

i) Published Information

1.0 Environment

PMRA Document Number	Reference
2138222	Environment Canada and Health Canada. 2001. Canadian Environmental Protection Act, 1999, Priority substances list assessment report, inorganic chloramines. Minister of Public Works and Government Services 2001. 72 pp.